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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,399	06/04/2007	Kazunari Hasebe	360882016200	9222
25227	7590	11/09/2010	EXAMINER	
MORRISON & FOERSTER LLP 1650 TYSONS BOULEVARD SUITE 400 MCLEAN, VA 22102				DELLA, JAYMI E
ART UNIT		PAPER NUMBER		
3739				
			NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

EOfficeVA@mofo.com

Office Action Summary	Application No.	Applicant(s)	
	10/584,399	HASEBE, KAZUNARI	
	Examiner	Art Unit	
	JAYMI DELLA	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 28 September 2010.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-14 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-4 and 8-10 is/are rejected.
 7) Claim(s) 5-7 is/are objected to.
 8) Claim(s) 11-14 are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 23 June 2006 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>12/28/2007, 11/15/2007</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application
	6) <input checked="" type="checkbox"/> Other: <u>E/C NPL Search, WO 96/15741</u> .

DETAILED ACTION

1. The following is a First Action, Non-Final Office Action on the merits. Claims 1-10 are addressed below.

Election/Restrictions

2. Applicant's election with traverse of Group I (claims 1-10) in the reply filed on 9/28/2010 is acknowledged. The traversal is on the ground(s) that "the Examiner has failed to analyze the claimed configuration of margin volume part (claim 1) and the claimed indicators (claim 11)." This is not found persuasive because the restriction requirement set forth a *shared* technical feature of the elastic tube which can be constricted and expanded by changing the radial size of the tube. Since, Eshel et al. (EP 0801938, previously cited) disclose this *common/shared* technical feature, it does not make a contribution over the prior art. The "margin volume part" and "plurality of indicators" in claims 1 and 11, respectively, are different, potentially special technical features, but Eshel discloses all of the common technical features.

3. The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 3-4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 3 recites: "...said elastic tube is connected to a predetermined branch passage for supplying a contrast agent, among the plural branch passages". However, on Page 8 and 16 of the specification and Fig. 1, the contrast agent is supplied through shift valve (31) to branch passage (23) which only connects to the main passageway of connector (20), and not the plural branch passages (i.e., 22, 23a). For purposes of examination, the claim will be interpreted as follows: ---- said elastic tube is connected to a predetermined branch passage for supplying a contrast agent to a main passage of the connector.--

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. **Claims 1-2 and 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Wallstén (WO 96/15741).**

8. Concerning **claim 1**, as illustrated in Fig. 1-2 and 5, Wallstén discloses a **heating-type balloon catheter device** (balloon heat treatment catheter 1; Pg. 4, ll. 2-5)

having a heating-type balloon (balloon 7) **at a top end portion** (distal end 3) **of a catheter main body** (catheter tube 15) **and a vibration imparting device** (device to impart an oscillating movement of fluid through container 21, catheter tube 15, and balloon 7 fixed jaw 65, movable jaw 67, rotary excenter disc 69, and motor not shown; Pg. 13, ll. 3-8) **connected to a base end portion of the catheter main body** (catheter tube 15 has base end portion at 11) **and configured to impart vibration to a liquid for heating in the heating-type balloon through a liquid for heating filled in the catheter main body** (oscillating movement device provides circulation of the liquid medium within balloon 7; Pg. 13, ll. 1-26), **said vibration imparting device comprising:**

an elastic tube with a base end portion thereof connected to said catheter main body and with a top end portion thereof closed, said elastic tube being filled with a liquid for heating (container 21 is formed as a tube and made of an elastic plastic film with good springing properties is connected at a base end 37 to catheter tube 15 and has a top end portion 35 that is closed via closure valve, and is filled with liquid for heating; Pg. 10, ll. 8-16, Pg. 13, ll. 12-26); **and**

a vibrator device having a roller configured to rotate about a rotary shaft at a position offset to the rotary shaft (vibrator device 65/67/69/motor not shown has a rotating excenter disc, or offset roller, 69);

wherein said elastic tube (21) is set to said vibrator device (65/67/69/motor not shown) so that a predetermined direction of rotation of said roller extends from the side of the base end portion of said elastic tube to the side of the top

end portion thereof and a margin volume part which is not pressed with said roller is provided on the side of the top end portion of said elastic tube (as roller 69 rotates in a predetermined direction indicated by arrow in Fig. 5, the roller extends from the top side of the base portion 37 of elastic tube 21 to the side of the top end portion 35 and a margin volume part between jaws 65,67 and closure valve 23 is provided on the side of the top end portion 35 of elastic tube 21 and is not pressed with roller 69; Pg. 13, ll. 12-26); and

wherein said elastic tube is configured to assume a shut-off state and a communication state in accordance with rotation of said roller in its predetermined direction, the shut-off state being a state in which the base end portion side of said elastic tube and the top end portion side thereof are blocked by pressing said elastic tube with the roller and reducing a radial size of said elastic tube with the roller and the communication state being a state in which the base end portion side of said elastic tube is communicated with the top end portion side thereof by enlarging and recovering the size of said elastic tube due to elasticity by releasing the pressing of said elastic tube with the roller (as roller 69 rotates around, it only contacts movable jaw 67 for a portion of its rotation, reducing the radial size of elastic tube 21 with the roller creating a shut-off state where there is blocked fluid communication between the top end portion 35 and base end portion 37; for the portion of rotation where roller 69 is not contacting movable jaw 67, a communication state is created where elastic tube 21 recovers its size and enlarges and

there is fluid communication between the top end portion 35 and base end portion 37

Pg. 10, ll. 8-16, Pg. 13, ll. 1-26); and

wherein the heating liquid in said elastic tube is supplied with pressure toward said margin volume part when said elastic tube is in the shut-off state while the heating liquid pressurized in said margin volume part is flown backward toward the base end portion side of said elastic tube when said elastic tube is in the communication state, in accordance with rotation of the roller in the predetermined direction of rotation of the roller (It is inherent that when roller 69 imparts a reciprocating movement to movable jaw 67 during the shut-off state that there is pressure supplied to the top end portion 35 and base end portion 37 of elastic tube 21, and thus, there is also pressure from top end portion 35 to closure valve 23, or the margin volume part. Then, when roller 69 is in the communication state, the pressure is released and the liquid in the margin volume part flows backward toward base end portion 37 of elastic tube 21).

9. Concerning **claim 2**, Wallstén discloses the elastic tube (21) is connected to the base end portion at (11) of catheter main body (15) through an extension tube (9) which is superior in rigidity from container (21) made of an elastic plastic film with good springing properties (Pg. 9, ll. 13-19 and Pg. 10, ll. 8-16; Fig. 1-2 and 5).

10. Concerning **claims 8-9**, Wallstén discloses at least one air vent valve (25) connected to the top end (35) of elastic tube (21) for withdrawing air in a predetermined path that is disposed on the predetermined path extending from base end portion at (11)

of catheter main body (15) to the top end portion (35) of elastic tube (21) (Pg. 11, ll. 14-28; Fig. 1 and 5).

11. Concerning **claim 10**, Wallstén discloses second air vent valve (25) as discussed above and first air vent valve (49, 55) connected to a path extending from catheter main body (15) to elastic tube (21) (Pg. 11-12, ll. 14-14; Fig. 1 and 4).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eshel (5,549,559).

15. Concerning **claim 1**, as illustrated in Fig. 1-3 and 8-9, Eshel discloses a **heating-type balloon catheter device** (thermal treatment catheter 2; Col. 3, ll. 28-29) **having a heating-type balloon** (inflatable cylindrical heating section 22; Col. 3, ll. 57-58) **at a top**

end portion (end of catheter 2 at anchoring section 21) **of a catheter main body** (long slender tube 20; Col. 3, ll. 54-55) **and a vibration imparting device** (peristaltic pump 6 engages peristaltic tube 66 and pumps liquid through the tube; Col. 4-5, ll. 65-10)

connected to a base end portion (23) of the catheter main body (20; Fig. 1) **and configured to impart vibration to a liquid for heating in the heating-type balloon through a liquid for heating filled in the catheter main body** (heating fluid is circulated, and thus inherently vibrating the liquid molecules, by peristaltic pump 6), **said vibration imparting device comprising:**

an elastic tube with a base end portion thereof connected to said catheter main body and with a top end portion thereof closed, said elastic tube being filled with a liquid for heating (peristaltic tube 66 has a base end portion at 68 and top end portion at 67 that is closed since it is connected to fluid reservoir 50; Col. 4, ll. 36-37, Col. 6, ll. 21-30; Fig. 7); **and**

a vibrator device having a roller configured to rotate about a rotary shaft at a position offset to the rotary shaft (pump 6 has a roller 65 configured to rotate about and a position offset to rotary shaft 62; Col. 4-5, ll. 65-9);

wherein said elastic tube (66) is set to said vibrator device (6) so that a predetermined direction of rotation of said roller extends from the side of the base end portion of said elastic tube to the side of the top end portion thereof and a margin volume part which is not pressed with said roller is provided on the side of the top end portion of said elastic tube (as roller 65 rotates in a predetermined direction indicated by arrow in Fig. 9, the roller extends from the top side of the base

portion at 68 of elastic tube 66 to the side of the top end portion at 67 and a margin volume part between top end portion at 67 and fluid reservoir 50 not pressed with roller 65; Col. 4-5, ll. 65-10, Col. 6, ll. 21-30); **and**

wherein said elastic tube is configured to assume a shut-off state and a communication state in accordance with rotation of said roller in its predetermined direction, the shut-off state being a state in which the base end portion side of said elastic tube and the top end portion side thereof are blocked by pressing said elastic tube with the roller and reducing a radial size of said elastic tube with the roller and the communication state being a state in which the base end portion side of said elastic tube is communicated with the top end portion side thereof by enlarging and recovering the size of said elastic tube due to elasticity by releasing the pressing of said elastic tube with the roller (As roller 65 rotates around, it pinches and reduces the radial size of elastic tube 66 to assume a shut-off state where the base end portion at 68 and top end portion at 67 are blocked from open fluid communication. Eshel fails to disclose the elastic tube to be configured to assume a communication state in accordance with rotation of said roller in its predetermined direction, the communication state being a state in which the base end portion side of said elastic tube is communicated with the top end portion side thereof by enlarging and recovering the size of said elastic tube due to elasticity by releasing the pressing of said elastic tube with the roller. However, at the time of the invention, it would have been obvious to one of ordinary skill in the art to use just one roller, instead of a plurality of rollers, in order to provide the benefit of a longer tube lifetime since there

is only one compression and expansion event per cycle leading to less friction, and thus heat, being generated. Thus, when only one roller 65 is rotating, there is also a communication state when the roller is not pinching any part of the tube (i.e., between portions 67 and 68 in Fig. 9); **and**

wherein the heating liquid in said elastic tube is supplied with pressure toward said margin volume part when said elastic tube is in the shut-off state while the heating liquid pressurized in said margin volume part is flown backward toward the base end portion side of said elastic tube when said elastic tube is in the communication state, in accordance with rotation of the roller in the predetermined direction of rotation of the roller (It is inherent that when roller 65 pinches elastic tube 66 during the shut-off state that there is pressure supplied to the top end portion at 67 and base end portion at 68 of elastic tube 66, and thus, there is also pressure from top end portion at 67 to fluid reservoir 50, or the margin volume part and that when roller 65 is in the communication state, the pressure is released and the liquid in the margin volume part flows backward toward base end portion at 68 of elastic tube 66).

16. Concerning **claim 2**, Eshel discloses the elastic tube (66) connected to the base end portion (23) of catheter main body (20) through an extension tube (25) which is more rigid than elastic tube (66) (Col. 3, ll. 67; Fig. 3).

17. Concerning **claim 3**, Eshel discloses a connector with three branch passages at base end portion (23) of catheter main body (20) and elastic tube (66) is connected to a

predetermined branch passage (25) and is capable of supply a contrast agent (Col. 3, ll. 67; Fig. 3).

18. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eshel (5,549,559), as applied to claims 1 and 3, in view of Shantha (5,195,965).

19. Concerning **claim 4**, Eshel fails to disclose the elastic tube connected to a predetermined branch passage of a shift valve nor the shift valve set to assume first and second positions. However, Shantha discloses a heating-type balloon catheter device (10) that includes a shift valve (51) such that in a first position a contrast agent is capable of being supplied via syringe (53) and communication between elastic tube (38) and catheter main body (12) is blocked, and a second position where communication between elastic tube (38) and catheter main body (12) is unblocked (Col. 5-6, ll. 66-19; Fig. 1). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have a shift valve in order to provide the benefit of an effective and simple mechanism for adjusting the pressure within the balloon as taught by Shantha (Col. 6, ll. 12-19).

Allowable Subject Matter

20. Claims 5-7 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

21. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: **Tamari (5,215,450), Neuwirth et al. (WO 94/10948), Eshel et al. (EP 0801938, cited in IDS), Noda et al. (6,146,411), Dann et al. (6,223,085), Drasler et al. (2001/0056257).**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAYMI DELLA whose telephone number is (571)270-1429. The examiner can normally be reached on M-Th 7:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571)272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. D./

/Thomas J Sweet/

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November 3, 2010

Supervisory Patent Examiner, Art
Unit 3779